COMMITTEE ON GOVERNMENT REFORM
TOM DAVIS, CHAIRMAN

NEWS RELEASE

For Immediate Release **October 13, 2004**
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DAVIS AND WAXMAN QUESTION FDA KNOWLEDGE OF CHIRON SUSPENSION

Washington, DC – As part of the House Government Reform Committee's ongoing inquiry into the nation's flu vaccine shortage, Chairman Tom Davis (R-VA) and Ranking Member Henry Waxman (D-CA) sent a letter today to Food and Drug Administration (FDA) Acting Commissioner Dr. Lester Crawford. The letter requests documents that can help shed light on what the FDA knew about the problems at the Chiron facility and whether FDA responded adequately.

A copy of today's letter follows:

October 13, 2004

Lester Crawford, D.V.M., Ph.D.
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Crawford:

On October 5, 2004, the British government's Medicines and Healthcare Products Regulatory Agency (MHRA) suspended the Chiron Corporation's influenza vaccine-manufacturing license effective immediately for three months because of manufacturing problems. The suspension prohibits Chiron from manufacturing, shipping, or marketing its Fluvirin vaccine. Chiron had planned to provide the U.S. between 46-48 million flu shots this year, almost half of the nation's supply. Officials from the Center for Disease

Control and Prevention (CDC), the Food and Drug Administration (FDA) and Chiron claim to have been informed of MHRA's decision on October 5, 2004. However, recent news reports raise questions about whether CDC and FDA officials had knowledge of the impending suspension of Chiron's license as early as September 13, 2004.

On October 8, 2004, the Committee held a hearing to examine the factors contributing to the influenza vaccine shortage. As a result of information obtained during the hearing and the recent news articles, the Committee is investigating the circumstances surrounding Chiron's suspension and whether any warning signs existed to indicate to CDC and/or FDA the possibility of a license suspension. Therefore, please produce the following documents to the Committee by October 20, 2004:

1. A copy of the Form 483 and the Establishment Inspection Report from FDA's June 2003 inspection of the Chiron's Liverpool Fluvirin facility;

2. Any and all copies of correspondence, meeting notes, and electronic communications between Chiron and FDA with regard to the deficiencies identified during the June 2003 inspection;

3. Any and all copies of correspondence, meeting notes, records of telephone calls, and electronic communications between Chiron and FDA subsequent to the company's August 25, 2004 announcement of contamination;

4. Any and all copies of records regarding communications between FDA and MHRA concerning the possibility of suspending Chiron's license to manufacture Fluvirin at the Liverpool facility; and

5. A timeline from August 1, 2004 to October 5, 2004 of actions taken by FDA, alone or in conjunction with Chiron, to remedy the problem of contamination at Chiron's Liverpool Fluvirin facility. This timeline should include, but not be limited to:

    a. the date FDA was first notified of the contamination, by Chiron and/or MHRA; and

    b. the date FDA was first notified of the possibility of Chiron's license suspension, by Chiron and/or MHRA.

Additionally, the Committee requests you make available for interviews those FDA employees who were responsible for inspections of Chiron's Liverpool Fluvirin facility and communications with the company from the June 2003 inspection to the present.

Thank you for your timely attention to this matter.

Sincerely,

Tom Davis
Chairman

Henry A. Waxman
Ranking Minority Member